

# Clin Ops Corner



*"There's lots going on in our corner of the world...and we want to tell it ALL!"*

*The Office of the  
Chief Medical Officer  
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## *Message from the Deputy Chief Medical Officer:*

This issue includes an update and clarification on the TRICARE Uniform Formulary, developments under the DoD Healthy Choices for Life Initiative, an update on Newborn Screening, and what's current in Medical Management. These topics are representative of the daily activities within the Office of the Chief Medical Officer. With each issue of Clin Ops Corner, we try to keep you informed of new developments in our corner of the world, and share lessons learned from recent cases, inquiries, and discussions.

Change can be challenging. We expect that the article on formulary changes will be of particular interest to clinicians. Please feel free to distribute this information widely to clinicians whose patients and practice may be affected. Information and preparation will help to smooth the implementation process.

**PLB**

**CAPT Patricia L. Buss, MC, USN  
TMA Deputy Chief Medical Officer**

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## ***Three Medications Selected For Non-Formulary Status***

*CAPT Patricia Buss, MC, USN  
TMA Deputy Chief Medical Officer*

On 19 April 2005, TRICARE announced the selection of the first three medications to be designated as non-formulary on the Uniform Formulary. The effective date for this change is 17 July 2005.

- The proton pump inhibitor esomeprazole (Nexium®)
- The angiotensin receptor blocker eprosartan (Teveten®)
- The angiotensin receptor blocker eprosartan in combination with hydrochlorothiazide (Teveten HCT®)

Please note that drugs listed as “non-formulary on the Uniform Formulary” are different than those drugs which are on the Uniform Formulary, but non-formulary at your local MTF. (See sidebar and below for additional information on the TRICARE Uniform Formulary.) The information provided herein refers only to Nexium, Teveten, and Teveten HCT – the first three drugs which will be on the non-formulary tier of the Uniform Formulary.

While the major impact of this change will be on beneficiaries who fill their prescriptions through the retail network or mail order program, implementation of this change will also impact MTF staff members who write or fill prescriptions.

Effective 17 July, MTFs may not have any of these three drugs on their local formularies. MTFs will be able to fill non-formulary requests for these agents only if **both** of the following conditions are met:

1. An MTF provider writes the prescription, and
2. Medical necessity is established for the non-formulary medication.

Active duty members pay no cost shares, but unless medical necessity is established, they may not obtain drugs that are non-formulary on the Uniform Formulary. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred by the MTF, as long as medical necessity has been established. Forms and specific procedures for establishing medical necessity will be available on the TRICARE Pharmacy website in late May 2005. In general, in order for medical necessity to be established, one or more of the following criteria must be met for **all** of the available formulary alternatives:

1. Use of formulary pharmaceutical agents is contraindicated;
2. The patient experiences or is likely to experience significant adverse effects from formulary pharmaceutical agents;
3. Formulary pharmaceutical agents result or are likely to result in therapeutic failure;
4. The patient previously responded to the non-formulary pharmaceutical agent, and changing to a formulary pharmaceutical agent would incur unacceptable clinical risk;
5. There is no alternative pharmaceutical agent on the formulary

Beginning July 17<sup>th</sup>, non-active duty beneficiaries who fill scripts for any of these three medications outside the MTF will pay \$22 for up to a 30 or 90-day supply, depending on whether they fill the prescription at a TRICARE Retail Network Pharmacy or through the TRICARE Mail Order Pharmacy. If medical necessity is established for using Nexium, Teveten or Teveten HCT, patients may qualify for the \$9 cost share for up to a 30-day TRRx supply or up to a 90-day TMOP supply. Active duty service members' cost share is \$0 in all points of service for all three tiers (formulary generic, formulary brand-name; non-formulary); however, active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary.

**Further information about the new TRICARE Uniform Formulary is available from your local P&T Committee, or from the following websites:**

<http://www.tricare.osd.mil/news/2005/news0509.cfm>

<http://www.ha.osd.mil/asd/20050425.cfm>

<http://www.tricare.osd.mil/pharmacy/>

Additional drug classes will be reviewed each quarter by the DoD Pharmacy and Therapeutics Committee, so you can expect additional drugs to be added to the non-formulary category every few months. ☼

## ***TRICARE Uniform Formulary: What Is It?***

*CAPT Patricia Buss, MC, USN  
TMA Deputy Chief Medical Officer*

**T**RICARE Management Activity (TMA) announced the publication of the Uniform Formulary final rule on April 1, 2004, in accordance with the requirement established in the fiscal year 2000 National Defense Authorization Act, Section 701, "Pharmacy Benefits Program." The final rule, effective May 3, 2004, established the process for placing prescription drugs into one of three cost-share tiers, based upon their relative clinical and cost effectiveness.

As the new structure is fully implemented, prescription drugs on the current Military Health System (MHS) formulary will be categorized as generic, formulary (brand-name), or non-formulary (diagram page 4). Prescription drugs are evaluated based on their relative clinical and cost effectiveness when compared with other drugs in the same therapeutic class. The process is guided by the Department of Defense (DoD) Pharmacy and Therapeutics (P&T)

Committee, comprising physicians and pharmacists. A Beneficiary Advisory Panel representing the general interests of all DoD beneficiaries has the opportunity to provide comments on Uniform Formulary recommendations before the Director, TMA determines whether to approve or disapprove the DoD P&T Committee's recommendations. The Uniform Formulary final rule does not change the TRICARE prescription drug benefit. The benefit includes those U.S. Food and Drug Administration approved drugs and medicines that by U.S. law require a physician's or other authorized provider's prescription, but does not include prescription drugs which are used in medical treatments or procedures which are expressly excluded from the TRICARE benefit by statute or regulation. The list of prescription drugs which are categorized as non-formulary will be published as the final determinations are made.

Under the Uniform Formulary, prescriptions filled by the TRICARE Mail Order Pharmacy cost \$3 for up to a 90-day supply of a generic medication, \$9 for up to a 90-day supply of a brand-name formulary medication, and \$22 for up to a 90-day supply of a non-formulary medication. Prescriptions filled using a retail network pharmacy cost \$3 for up to a 30-day supply of a generic medication, \$9 for a 30-day supply of a brand-name formulary medication, and \$22 for up to a 30-day supply of a non-formulary medication.

Beneficiaries choosing to fill prescriptions using

a non-network pharmacy pay either \$9 or 20 percent of the total cost of the prescription, whichever amount is greater, for both generic and brand-name formulary medications; and \$22 or 20 percent, whichever amount is greater, for up to a 30-day supply of non-formulary medications. Applicable deductibles for non-network pharmacy use must first be met.

Up-to-date information on the TRICARE Pharmacy Program is available on the TRICARE Web site at [www.tricare.osd.mil/pharmacy](http://www.tricare.osd.mil/pharmacy).

### **Uniform Formulary:**

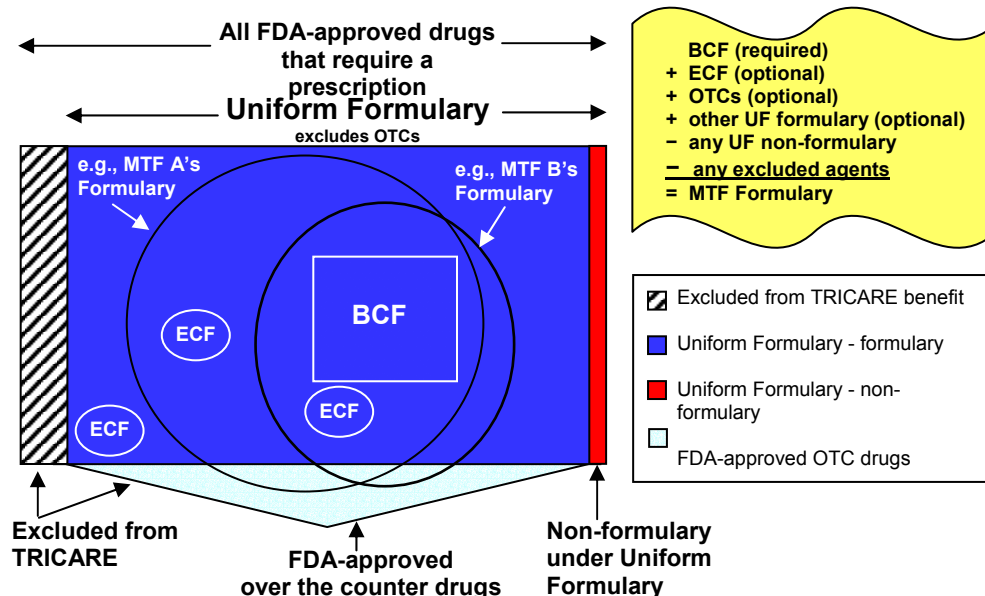
- All FDA-approved prescription medications, except those expressly excluded from the TRICARE benefit by statute or regulation.
- Applicable to all DoD pharmacy venues.
- UF agents are divided into formulary and non-formulary drugs, with three cost-sharing tiers: generic, formulary (brand-name), and non-formulary.
- No drug on the UF can be moved from formulary to non-formulary status unless recommended by the DoD Pharmacy and Therapeutics Committee, reviewed by the DoD Beneficiary Advisory Panel, and approved by the Director, TRICARE Management Activity.
- Non-formulary agents are available through the TMOP and retail pharmacies at the non-formulary cost-share.
- Drugs on the uniform formulary may be on Military Treatment Facility (MTF) formularies, unless prohibited by National Pharmaceutical Contract language.
- Drugs selected to the UF non-formulary category may not be on MTF formularies.

### **Basic Core Formulary:**

- A subset of the Uniform Formulary. The BCF is applicable only to the direct care system.
- A list of medications that are required to be on all MTF formularies.
- Offers clinical and/or economic advantages over competing agents.
- Intended to meet the majority of primary care needs of Military Health System (MHS) beneficiaries.
- Contains drugs in some therapeutic drug classes, including statins, leutinizing hormone releasing hormone agonists, and triptans, that provide system wide cost avoidance through committed use of National Pharmaceutical Contracts.
- The DoD Pharmacy & Therapeutics Committee is responsible for changes to the BCF and conducts reviews at its quarterly meetings.

# TRICARE Uniform Formulary

## As Implemented in MTFs



### Extended Core Formulary:

- a subset of the Uniform Formulary. The ECF is applicable only to the direct care system.
- The ECF is a list of medications that may be on MTF formularies, if providers at that MTF require agents from that therapeutic class for the scope of care that is provided at the MTF beyond primary care. Drugs selected for the ECF offer clinical and/or economic advantages over competing agents.
- ECF agents are intended to meet specialty care needs of MHS beneficiaries, but may sometimes be appropriate for use by primary care providers.
- If the MTF Pharmacy & Therapeutics Committee determines that a drug class is necessary to support the MTF's scope of practice, then the MTF must have all ECF agents within that class on the MTF's formulary.
- The DoD Pharmacy & Therapeutics Committee is responsible for changes to the ECF and may conduct reviews during drug class reviews at its quarterly meetings.

To read the Final Rule establishing the Uniform Formulary (Federal Register, Vol 69, No. 63, page 17035 April 1, 2004, "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Implementation of the Pharmacy Benefits Program") go to:

<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-7219.pdf>. The regulation itself, 32 Code of Federal Regulations Part 199.21, is at: <http://www.tricare.osd.mil/cfr/C21.PDF>. ☞

### This Month's Who's Who:

*David R. Arday, MD, MPH  
CAPT, MC, USPH  
TMA, Medical Epidemiologist  
Office of the Chief Medical Officer*

CAPT David R. Arday, MD, MPH, has joined TMA/OCMO as a medical e. Dr. Arday is board certified in both general preventive medicine and public health, and in occupational medicine. Most of his prior assignments have involved either medical administration or health care research. He came to OCMO from Dept. of Homeland Security, National Disaster Medical System, where he served as Chief Medical Officer. Prior to that he was a medical epidemiologist detailed to the Army Medical Surveillance Activity, located at Walter Reed.

He has considerable experience in data analysis and interpretation, both medical administrative data and survey data.

Dr. Arday received his medical degree from Case-Western Reserve U. School of Medicine, and his MPH from Johns Hopkins U. School of Hygiene and Public Health. He completed his residency in general preventive medicine and public health at Walter Reed Army Institute of Research. He later trained as a medical epidemiologist in the Centers for Disease Control and Prevention's Epidemic Intelligence Service (EIS). He has been a U.S. Public Health Service Officer since 1992. He served with the U.S. Army from 1979 to 1992. Dr. Arday has authored 22 peer reviewed manuscripts or book chapters, 8 other published articles or reports, and 22 abstracts or other scientific presentations. He was elected to Fellowship in the American College of Preventive Medicine in 2002. ☞

## ***TOBESAHOL: A Vital Part of DoD's Healthy Choices for Life Initiative***

***LCDR Robert Fry, MSC, USN, Ph.D., Program Manager, DoD Population Health  
Mr. Frank Little, MSA, MSW, Senior Health Policy Analyst***

***According to the Centers for Disease Control and Prevention, in 2000, tobacco use, poor diet and physical inactivity, and alcohol consumption were leading actual causes of death in the United States. Actual causes of death are defined as lifestyle and behavioral choices that contribute to this nation's leading killers including heart disease, cancer, and stroke.***

In June 2004, as part of the Department of Defense's Healthy Choices for Life Initiatives, the Assistant Secretary of Defense for Health Affairs announced a strategic three pronged approach to reduce the number of active duty and family members who use tobacco, are overweight or obese, and drink heavily. These strategies were later coined as "TOBESAHOL" for tobacco, obesity, and alcohol.

The TOBESAHOL Projects include two web-based demonstration projects for Tobacco Cessation and Weight Management, and a pilot project for web-based Alcohol Prevention Education. The DoD Military Health System proposes to implement and evaluate under the Healthy Choices for Life Initiatives: A Tobacco Cessation Quitline Demonstration project, a Weight Management Demonstration project, and an Alcohol Web-based Prevention Education Pilot Project

***These strategies were later coined as "TOBESAHOL" for tobacco, obesity, and alcohol.***

The Tobacco Cessation Demonstration project is being done to measure the effectiveness of a toll-free telephone Tobacco Quitline and the use of prescription pharmacotherapy by eligible beneficiaries. This Demonstration will enable DoD to evaluate selected interventions in a DoD beneficiary population and gather data for health care costs and utilization. The Demonstration project plans for data to be gathered on demonstration participants in four states (Colorado, Kansas, Missouri and Minnesota). The Demonstration will continue based on outcome measures related to utilization rates, quit rates, and success of pharmacotherapy. This demonstration project is being conducted under the expanded HMO Uniform Benefit of the 32 CFR part 199.18 (b)(2). The Tobacco Cessation Demonstration project will provide information that will enable DoD to determine whether behavior modification, either alone or with pharmacotherapy, should be added to the TRICARE benefit for the treatment of patients who use or are dependent upon tobacco.

The Weight Management Demonstration project will allow the DoD to determine the efficacy and acceptability of distance behavioral interventions and pharmacotherapy in producing and maintaining clinically significant weight loss in at-risk overweight or obese individuals. The Weight Management demonstration project plans for data to be gathered on demonstration participants in four states (Indiana, Illinois, Michigan, and Ohio). The Demonstration will continue based on outcome measures related to program utilization rates, success in achieving desired weight loss, reduction in body mass index, weight loss maintenance, and use of pharmacotherapy that contributed to weight loss. This Demonstration project is being conducted under the authority of 10 U.S.C. 1092. The Weight Management Demonstration project will provide information that will enable DoD to determine whether to seek a change in statute to authorize, as part of the TRICARE benefit, behavior modification either alone or with pharmacotherapy for the treatment of patients that are overweight or obese.

The Web-based Alcohol Abuse Prevention Education Pilot project is an eight installation (two installations per Service) pilot project for active duty service members that will allow DoD to test the effectiveness of this intervention in a repeated measures study with control groups. Both the control group and the intervention group will continue with their Service-level alcohol and substance abuse training. The intervention group will be provided with web-based education in addition to their regular Service-level training. The Web-based Alcohol Prevention Education offers a personalized interactive intervention program. These courses represent a new and innovative approach to education that young active duty members can relate to and feel comfortable with. Such an approach combines proven science-based teaching with the latest web-based media technologies. The demonstration project is

targeted at the 18-25 year old active duty drinkers to support the DoD alcohol goal and message of “responsible consumption.”

The MHS leadership has taken the first step towards transforming the MHS from a reactive to a proactive healthcare system. The TOBESAHOL projects will aid in creating agile forces and families by helping them align healthy choices for life. ☞

## *Comprehensive Newborn Metabolic Screening*

*COL John P. Kugler, MC, USA*

*TMA Deputy Medical Director*

*Office of the Chief Medical Officer*

Annually, nearly 1800 infants are born in the U.S. with treatable metabolic disorders that are not being screened for on a regular basis and that will severely injure or kill newborns if not detected. Tremendous variance in Newborn Screening (NBS) is evident among the states. All states individually mandate screening newborn infants for inborn errors of metabolism and genetic disorders. However, because there is no national screening requirement, there is great disparity in tests performed and associated follow-up procedures. Some states require screening for as few as four conditions and some for more than 30—most states screen for 8 or fewer disorders. Screening for three conditions (PKU, congenital hypothyroidism, and galactosemia) is mandated in all 50 states. Sickle cell disease screening is mandated in all but 2 states. This variance is magnified in MTF's where there is not a mandated obligation to follow individual state standards. Some MTF's use the state standards and lab where they are located, whereas as other MTF's, especially those in OCONUS locations, use state or commercial labs in different locations and with different standards. In addition, frequent deployments and transfers of providers and military families stress follow-up procedures and highlight the need for a comprehensive, uniform standard.

***The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS) commissioned the American College of Medical Genetics (ACMG) to study and make specific recommendations on comprehensive metabolic screening in the U.S.***

ACMG's recommendations were recently completed and submitted for 60 day public comment on 8 March 2005 (<http://mchb.hrsa.gov/screening/>). Their main recommendation was for a significant expansion of comprehensive newborn metabolic screening among the states with standardized reporting, tracking, and follow-up.

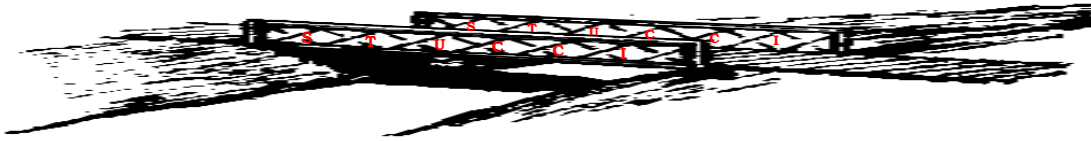
Until recently, routine screening of newborns for inherited metabolic disorders was limited to three to five disorders using biochemical testing methods. Now, with a new “state of the art” method using tandem mass spectrometry (MS/MS), more than 50 diseases or disorders can be easily detected from a single drop of blood. A tandem mass spectrometer is able to detect the presence of certain diseases by separating out molecules in a specimen by their weight. The speed of MS/MS makes it well equipped to handle the large number of samples that are processed in newborn screening programs. Furthermore, the approach is more precise and accurate than existing tests and the rate of false positives is very low. In particular, MS/MS is more accurate than most methods now in use for PKU and other amino acidemia disorders.

Currently, specialty consultants in neonatology, pediatrics, family medicine, nutrition, laboratory, and pathology for the three services have been working with the Office of the Chief Medical Officer at TMA and have started an intensive study of initiatives to standardize and expand newborn metabolic screening throughout the MHS. Particular focus has been on options that would facilitate 1.) The more widespread use of expanded testing with tandem mass spectrometry technology (expanding screening to the 54 conditions recommended by the ACMG); 2.) Exploration of options to provide timely electronic feedback of results to MTF's along with practice guidelines and consultative services; and 3.) The initiation of ground work for a comprehensive birth registry for tracking DoD newborns. More to follow on this as the workgroup continues its evaluation and specific recommendations are formulated. ☞

# Case Management Bridge Crossings

*Bridging the Chasms of Case Management . . . making it a reality*

*Lourie R. Moore, Maj, USAF, NC*



**D**r. Winkenwerder, the Assistant Secretary of Defense for Health Affairs, stated that the Department of Defense (DoD) will spend almost \$37B on health care in fiscal year 2005, projecting to exceed \$50B within five years. So, how can the Military Health System (MHS) control the rapidly rising costs of health care? Read the following information for “*the rest of the story.*”

In the Direct Care System (DCS), military treatment facilities (MTFs) are directed to establish Medical Management (MM) Programs to assist in providing quality, cost-efficient health care to their beneficiaries. MM is an integrated care model that promotes Utilization Management (UM), Case Management (CM), and Disease Management (DM) as a hybrid approach to managing patient care.

But how do you describe CM? One might start by describing the person or role: educator, facilitator, coordinator, “healthcare system navigator,” patient champion. In the military setting, the CM is defined as “a collaborative process under the population health continuum, which assesses, plans, implements, coordinates, monitors, and evaluates options and services to meet an individual’s health needs through communication and available resources to promote quality, cost-effective outcomes.” The targeted patient population is often those with catastrophic or chronic conditions. The case manager is a valuable asset to any healthcare team and organization since he/she has the ability to optimize patients’ clinical outcomes and decrease healthcare costs.



So, the question often posed is “how exactly can CM decrease healthcare costs? How can case managers objectively show a positive return on investment (ROI)?” One method for demonstrating a measurable value of CM and calculating ROI for CM is to translate the case manager’s actions into the ability to enhance clinical outcomes, consequently resulting in improved financial outcomes or care/cost avoidance.

Case managers, along with disease managers, have the opportunity to impact the cost of health care by assisting patients to adhere with their prescribed medication therapy.

There are 92 million prescriptions filled annually in the MHS: 53M in the MTFs (total of 536), 34M in retail pharmacies (total of 54,000), and 4.7M via the TRICARE Mail Order Pharmacy (TRICARE Conference Brief, 2005). In 2004, \$5B (28% of the total Defense Health Plan) was spent on pharmacy costs, an increase of 18% of the previous year. Of that total, \$1.9M was spent in the DCS, while the larger portion of \$2.3B was spent in retail pharmacies. The increasingly high pharmacy costs started with the implementation of the TRICARE Senior Prime benefit in 2001.

While the data is more difficult to ascertain in MHS, private sector statistics related to medication therapy range from patients failing to fill their prescriptions (12%); failing to take their medications after they are filled (12%); to failing to continue taking medications (29%) as ordered (American Hospital Association in CMAG Training Book, 2002). Although MTF pharmacists play a major role in monitoring and managing patients’ medication treatments, case and disease managers should partner with them, as well as primary care providers, to help educate patients, especially those with polypharmacy needs, about their medications, and promote adherence. Case managers can help patients through education, monitoring treatment, and providing positive reinforcement.

To demonstrate the value of their services, case managers could calculate the cost of the prescribed medications their patients had continued to take/not wasted due to adherence to their medication treatment (e.g., cost avoidance). Consequently, medication adherence may also result in “soft savings” of improved morbidity and mortality, avoided hospitalizations, and improved quality of life. More information regarding determining cost avoidance and ROI may be found in the MM Guide, Section II, Case Management and Section V, Medical Management Measures.

In 2004, the Case Management Society of America (CMSA), in collaboration with Pfizer, Inc., developed their Case Management Adherence Guidelines (CMAG) as their approach to demonstrating the value of case management. CMAG is a comprehensive, evidence-based program that provides case managers with the necessary training, tools, and interventions to assist patient's adherence with their medication therapy (CMSA, 2004). For more information on the Guidelines, click [here](#). The article titled Enhancing adherence to Long-Term Medical Therapy: A New Approach to Assessing and Treating Patients, which described the CMSA's CMAG, will be available for download at the PHMMD Support Center library.

The CMAG program addresses reasons why patients may not continue taking their medications. It includes an assessment of patient motivation and medical knowledge/health literacy. Available to CMSA members only, case managers have access to the CMAGTracker. CMAGTracker is a web-based tool used to administer the CMAG's assessment and interventional tools for patients enrolled into the CMSA's outcomes study. To assist with the process, case managers are also trained in motivational interviewing techniques, which are a directive, patient-centered method to assess a patient's readiness to change and motivate behavioral change. More information about this is available on CD ROM, which is available during the CMAG training.

The CMSA provides free training on how to use the CMAG. Training is also available for military case managers. If interested, please contact Maj Moore to coordinate a training session. To demonstrate outcomes related to using the CMAG, the CMSA also initiated a national CMAG research study in which case managers using the CMAGTracker tool may choose to enroll. TRICARE Management Activity is also interested in establishing a similar research study customized to the MHS. Interested case managers should contact Maj Moore. For more information on CMSA's CMAG's research study, click [here](#).



### Small Bytes

- The annual **Case Management Society of America (CMSA)** conference, including a Military Track, will be held 22-25 Jun 05 in Orlando, FL. For more information, see the [CMSA website](#).
- The **Extended Care Health Option (ECHO)** will be implemented 1 Sep 05. Government and contract personnel met in May to discuss implementation processes/plans. TMA is developing training plans for MTF staff. Beneficiaries currently utilizing the Program for Person with Disabilities (PPPWD) will receive more information in the mail once marketing materials are finalized. More information to follow.
- You can now register online for the **“Medical Management in Today's TRICARE Environment” course**. Check the [PHMMD Support Center, Conferences and Training site](#), for more information on the 2005 courses. Registration for the course is *different* from registration for the distance learning modules in the Learning Center. A username and password is not necessary for the MM Course registration.
- The **Medical Management Guide**, Version 1.0, Jan 05 (draft), is available as an Adobe Acrobat pdf document. The entire Guide is available for download at the [PHMMD Support Center website](#).



### Note from the Editor

*Your feedback is very important to us! Continue to let us know what you think and share with us what you know. If you would like to subscribe to Clin OpsCorner simply send an email to [listserv@listserver.tma.osd.mil](mailto:listserv@listserver.tma.osd.mil). Put “subscribe clinicalquality” in the subject line (clinicalquality is ONE word.)*